

In re Application of: Tamar HAREL et al
 Serial No.: 10/526,708
 Filed: September 20, 2005
 Office Action Mailing Date: July 14, 2008

Examiner: FLORY, Christopher A.
 Group Art Unit: 3762
 Attorney Docket: 34490

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-37, 39-44, 49-56 and 61-67 are now pending in this Application.

Claims 1, 2, 6, 9, 16-19, 30, 33, 34-37, 39-44, 57-63 and 65 have been rejected under 35 U.S.C. § 102. Claims

1-37, 39-44, and 49-67 have been rejected on the grounds of nonstatutory obviousness-type double patenting. Claims 49-56 have been rejected on the grounds of statutory type double patenting. Claims 1, 34, 30, 34, 49 and 61-63 have been amended herewith. Claims 57-60 have been cancelled without prejudice.

Amendments To The Claims

Claim Objections

Claim 49 has been objected to because of the following informalities: the portion of line two which reads "at least electrode" should be corrected to read "at least one electrode". Applicant amended claim 49 according to the Examiner remarks. Thus, Applicant believes that the objection to Claim 49 should be withdrawn.

35 U.S.C. § 102 Rejections

The Examiner rejected claims 34, 36 and 40 under 35 USC 102(b) as being anticipated over U.S. Patent 4,428,366 of Findl et al (hereinafter: *Findl*)

The Examiner rejected claims 34-36 and 40 under 35 USC 102(b) as being anticipated over U.S. Patent 5,031,617 of Klettner et al (hereinafter: *Klettner*).

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In order to clarify the scope of the claimed invention according to the differences between *Findl* and *Klettner* and the present invention, Applicant has amended independent claim 34, emphasizing the distinctiveness of the claimed invention in the light of *Findl* and *Klettner*.

The Examiner is of the opinion that *Findl* and *Klettner* disclose apparatuses for blood glucose control which are capable of applying an electric field, as recited in claim 34.

Though Applicant recognizes that the present invention, *Klettner* and *Findl* are capable of applying an electric field, Applicant believes that the present claims as amended are distinguished over *Findl* and *Klettner* teachings in essential features.

One of the distinguishing features relied upon is that amended claim 34 discloses an apparatus having for an implanted electrode for applying an electric field to affect a pancreas using an implanted electrode, see FIG. 1 and related description of the present application. In contrary, *Findl* describes a non-invasive technique for applying a uniform, monopolar pulsed magnetic field using a stationary device, such as Helmholtz-type electromagnet; see Abstract and FIG. 15 of *Findl*. Similarly, *Klettner* describes apparatus for altering human blood glucose levels by the application of electric charge that is applied by an stationary electrostatic generator, such as a Wimshurst apparatus or a Van de Graaff generator, which are stationary generators producing electrical discharges at high voltage. In particular, *Klettner* applies the electric charge through points of contact between the electrostatic

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generator and the body of the patient, for example the palms and the soles, see column 2, lines 40-60 and Example 1 of the present application.

As neither *Findl* nor *Klettner* teach or imply any electrode for applying any electric field, it is clear that *Findl* and *Klettner*, alone or in combination, do not include any evidence or suggestion pertaining to an implanted electrode for applying an electric field to affect a pancreas, as disclosed in amended claim 34. It should be noted that as *Findl* and *Klettner* teach and suggest stationary devices which are designed for immobile patients, they are actually teaching away from the claimed invention that allows monitoring ambulatory patients, see page 55, lines 25-35 of the present invention.

As the aforementioned distinguishing feature of amended claim 34 is not described in *Findl* and *Klettner*, either expressly or inherently, it is clear that *Findl* and *Klettner* do not anticipate that amended claim 34.

The Examiner rejected claims 1, 2, 6, 9, 16-19, 30, 33, 36, 37, 57-63 and 65 under 35 USC 102(b) as being anticipated over U.S. Patent 5,919,216 of Houben et al (hereinafter: *Houben*). The Examiner assumes that claims 34, 35 and 39-44 as stand rejected.

Though Applicant recognizes that both the present invention and *Houben* describe an implanted device capable of applying an electric field, Applicant believes that the present claims as amended are distinguished over *Houben* teaching in essential features.

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One of the distinguishing features relied upon is that the amended claim 34 discloses *an apparatus for blood glucose control having at least one implanted electrode and a circuitry for electrifying said at least one implanted electrode in a manner which compensates for a loss of acute response to a glucose ingestion event by said pancreas, wherein said circuitry reduces or prevents a substantial increase in insulin secretion during said compensation*, see for example page 63, lines 5-20 of the present application.

Though *Houben* describes an implanted electrode for applying an electric field it does not describe a *circuitry that compensates for a loss of acute response to a glucose ingestion event by said pancreas and reduces or prevents a substantial increase in insulin secretion* during said compensation. As commonly known in the art, a normal pancreas is expected to exhibit an acute response to an ingestion event by providing an initial bolus of glucose and to cause the shutting down of glucose secretion by the liver (albeit, at a time delay). The *circuitry* disclosed in amended claim 34 *compensates for the loss of such an acute response while reducing or preventing a substantial increase in insulin secretion*.

Houben's implanted electrode is adapted for enhancing insulin production in a patient who needs insulin treatment, see column 3, lines 10-15 of *Houben*. As such, *Houben* is adapted to stimulate earlier depolarization bursts to increase insulin production and/or to shorten the insulin-producing bursts and reduce insulin production., see the abstract, column 3, lines 32-40 and FIG. 2A of *Houben*. However, *Houben* does not teach or imply a *circuitry that compensates for a loss of acute*

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response as disclosed in amended claim 34. As *Houben* teaches direct stimulus of insulin increasing or decreasing bursts, as emphasized in *Houben's* the abstract, and not compensating for the loss of acute *responses to glucose ingestion events*, it actually teaching away from the circuitry described in amended claim 34.

As the aforementioned distinguishing feature of amended claim 34 is not described in *Houben*, either expressly or inherently, it is clear that *Houben* does not anticipate that amended claim 34.

Reference is now made to amended claim 1. The arguments made above in respect of the novelty of claims 34 apply *mutatis mutandis* to independent claim 1. In particular, amended claim 1 discloses a method and an implanted apparatus of glucose level control that includes applying an electric field to affect the pancreas using implanted electrode such that blood glucose levels are significantly reduced and blood insulin levels are not significantly increased. As described in relation to claim 34, *Houben* teaches controlling insulin levels by direct stimulus of insulin increasing or decreasing bursts. *Houben* does not teach or imply applying electric fields for reducing blood glucose levels without significantly increasing blood insulin levels, as disclosed in amended claim 1. As the aforementioned distinguishing feature of amended claim 1 is not described in *Houben*, either expressly or inherently, it is clear that *Houben* does not anticipate that amended claim 1.

Reference is now made to amended claim 30. The arguments made above in respect of the novelty of claims 34 apply *mutatis mutandis* to independent claim 30. In particular, amended claim 30 discloses a method and an implanted apparatus for

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applying an electric field to affect the pancreas operative to reduce blood glucose levels if elevated and not significantly reduce such levels if not substantially elevated.

It should be noted that such an electric field is important for avoiding damage which may be caused by applying electric fields which can reduce low blood glucose levels.

As described in relation to claim 34, *Houben* teaches controlling insulin levels by direct stimulus of insulin increasing or decreasing bursts. *Houben* does not teach or imply such an electric field, as disclosed in amended claim 30. As the aforementioned distinguishing feature of amended claim 30 is not described in *Houben*, either expressly or inherently, it is clear that *Houben* does not anticipate amended claim 30.

Reference is now made to amended claim 61. The arguments made above in respect of the novelty of claims 34 apply *mutatis mutandis* to independent claims 61. In particular, amended claim 61 discloses a method of *controlling blood glucose* by *electrifying an implanted electrode to apply electric field to affect a pancreas in accordance with a fixed protocol, wherein the electrifying comprises electrifying irrespective of blood glucose level*. As described in relation to claim 34, *Houben* teaches controlling insulin levels to enhance glucose production. As such, *Houben* teaching describes applying electric field in relation to blood glucose level and therefore teaching away from the method disclosed in amended claim 61 in which electric field is applied *irrespective of blood glucose level*. As the aforementioned distinguishing feature of amended claim 61 is not described in *Houben*, either expressly or inherently, it is clear that *Houben* does not anticipate amended claim 61.

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Based on the above, Applicant asserts that the amended independent claims 1, 30, 34, and 61 are allowable main claims and that respective dependent claims are consequently allowable as being dependent on an allowable main claim. Claims 57-60 have been cancelled without prejudice.

Non-statutory Obviousness-type Double Patenting

The rejections

Claims 34-37, 39-44 and 49-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 52-55, 79-81 and 86 of copending Application No. 10/804,560.

Claims 1-29 and 57-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 and 27-30 of copending Application No. 10/570,576.

Claims 30-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-38 of copending Application No. 10/570,576. The Examiner argues that although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to reduce glucose levels in an acute manner.

Claims 34-37, 39-44 and 53-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 39-49 of copending Application No. 10/570,576. The Examiner argues that although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to use a non-excitatory electrical field when stimulating the pancreas.

Discussion

Applicant respectfully requests that the obviousness double patenting rejections be held in abeyance until the indication of allowable claims.

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Statutory-type Double Patenting

The rejections

Claims 49-56 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 56-63 of copending Application 10/570,576.

Discussion

Claims 49-56 have been amended and now differ from claims 56-63 of copending Application 10/570,576. Applicant assumes that this nonstatutory double-patenting rejection is moot.

In view of the above amendments and remarks it is respectfully submitted that claims 1-37, 39-44 49-56 and 58-67 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,


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Date: December 15, 2008

Enclosures:

- Petition for Extension (Two Months)